IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE

DENTSPLY INTERNATIONAL, INC.	
Plaintiff,	
v.	Civil Action No JURY DEMAND
US ENDODONTICS, LLC	JOKT DEIVINIAD
Defendant.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Dentsply International, Inc. ("Plaintiff" or "Dentsply"), for its Complaint against Defendant US Endodontics, LLC ("US Endo" or "Defendant"), states as follows:

NATURE OF ACTION

1. This is an action arising under the patent law of the United States, 35 U.S.C. § 1, et seq., for infringement by Defendant of United States Patent Nos. 8,727,773 ("the '773 patent") and 8,562,341 ("the '341 patent") (collectively the "Asserted Patents" or the "Patents-in-suit").

PARTIES

- 2. Plaintiff Dentsply International, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 221 West Philadelphia Street, York, PA 17405.
- 3. Dentsply is a well-known leading manufacturer and distributor of dental and other consumable products in the healthcare product industry in the United States and abroad. Dentsply's broad global product platform helps dental professionals serve patients' oral health care for a lifetime, from preventive services to tooth replacement. Dentsply's oral health

products range from general dental consumables and laboratory products to products supporting the dental specialty markets of orthodontics, endodontics and implants.

4. On information and belief, Defendant US Endodontics, LLC is a limited liability company organized and existing under the laws of the State of New Mexico, having a place of business at 309 Wesley Street, Johnson City, TN 37601. US Endo is registered to do business in the State of Tennessee with the Tennessee Secretary of State. US Endo may be served with process in the State of Tennessee through its registered agent, Bobby Bennett, at 309 Wesley Street, Johnson City, TN 37601.

JURISDICITON AND VENUE

- 5. This action arises under the Patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
 - 6. Venue is proper in this district under 28 U.S.C. §§ 1391(c) and 1400(b).
- 7. On information and belief, Defendant US Endo is subject to personal jurisdiction in this district by virtue of its presence in this State, having conducted business in this State, having availed itself of the rights and benefits of Tennessee law such that it should reasonably anticipate being haled into court in this judicial district, having engaged in systematic and continuous contacts with the State of Tennessee, and in particular within this judicial district, and from the receipt of substantial revenue from activities conducted in this state and in this judicial district.

U.S. Patent No. 8,727,773

8. On May 20, 2014, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,727,773 entitled "Dental and Medical Instruments Comprising

Titanium" to Gold Standard Products, Inc. as assignee of the inventor Dr. Neill H. Luebke. A true and correct copy of the '773 patent is attached hereto as Exhibit A.

- 9. Dentsply is the exclusive licensee for the '773 Patent and has the right to bring suit for infringement and to recover for all past, present and future damages.
- 10. The '773 Patent relates generally to a method of manufacturing or modifying a dental instrument or device where a dental instrument or device is provided having an elongated shank of super-elastic nickel titanium alloy and then subsequently heat-treating the entire instrument or device at 400°C or above but not the melting temperature, resulting in a device with shape memory characteristics including an angle of greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion. *See* Ex. A.

<u>U.S. Patent No. 8,562,341</u>

- 11. On October 22, 2013, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,562,341 entitled "Dental and Medical Instruments Comprising Titanium" to Gold Standard Products, Inc. as assignee of the inventor Dr. Neill H. Luebke. A true and correct copy of the '341 patent is attached hereto as Exhibit B.
- 12. Dentsply is the exclusive licensee for the '341 Patent and has the right to bring suit for infringement and to recover for all past, present and future damages.
- 13. The '341 Patent relates generally to a method of manufacturing or modifying a dental instrument/device where a dental instrument or device is provided having an elongated shank of super-elastic nickel titanium alloy and then subsequently heat-treating the entire instrument or device at 400°C or above but not the melting temperature, resulting in a device with shape memory characteristics including an angle of greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion. *See* Ex. B.

DEFENDANT'S ACTS OF INFRINGEMENT

- 14. Non-party, Edge Endo, LLC ("Edge Endo"), maintains a website at <www.edgeendo.com>. Edge Endo provides information to the public regarding its products, including the Edge File X1, Edge File X5 and Edge File X7 endodontic dental files on its website.
- 15. On information and belief, Edge Endo's website is directed to marketing, offering for sale and selling the EdgeFile X1, Edge File X5 and Edge File X7 endodontic dental files in the United States, and in the Eastern District of Tennessee.
- 16. According to information provided to the public by Edge Endo, the EdgeFile X1, X5 and X7 use "an Annealed Heat Treated (AHT) nickel-titanium alloy." *See* Ex. C (a true and correct copy of product information for EdgeFile X1, X5, and X7 printed from http://edgeendo.com). Edge Endo also provides information to its customers and potential customers indicating that the EdgeFiles have "no shape-memory," and can be "pre-bent" to retain a curved shape. *See* Ex. D (a transcript of a video by Edge Endo founder Chuck Goddis, DDS, entitled "EdgeFile Product Features" found at http://edgeendo.com/videos/).
- 17. Upon information and belief, Defendant US Endo manufactures the Edge File X1, File X5, and File X7 endodontic dental files for Edge Endo. *See* Exhibit E (a true and correct copy of information retrieved from the United States Food and Drug Administration ("FDA") Medical Device Establishment Registration and Device Listing Database identifying US Endo as the manufacturer of EdgeFiles).
- 18. On information and belief Defendant US Endo manufactures, purchases, obtains or otherwise procures from third parties endodontic dental files having an elongated shank of superelastic nickel titanium alloy ("untreated files").

- 19. On information and belief, Defendant US Endo manufactures post-heat treated endodontic dental files, including but not limited to the EdgeFile X1, X5 and X7 using a method that infringes at least one claim of each of the Patents-in-Suit.
- 20. On information and belief, Defendant's manufacture, use, offer to sell, marketing, sale and/or distribution of at least the EdgeFile X1, X5 and X7 within the United States, or importation of these products into the United States during the term of the Patents-in-suit infringes at least claim 1 of the '773 Patent pursuant to 35 U.S.C. § 271.
- 21. On information and belief, Defendant's manufacture, use, offer to sell, marketing, sale and/or distribution of the EdgeFile X1, X5 and X7 within the United States, or importation of the products into the United States during the term of the Patents-in-suit infringes at least claim 1 of the '341 Patent pursuant to 35 U.S.C. § 271.
- 22. Defendant US Endo has knowledge of the Patents-in-suit at least through the filing of the present lawsuit. Upon information and belief, US Endo was aware of certain patent applications that had been filed by Dr. Neill Luebke when it began manufacturing the EdgeFile products. The Patents-in-Suit claim priority to the earlier Luebke applications of which US Endo was aware by May 2012.
- 23. Tulsa Dental Products, LLC d/b/a/ Tulsa Dental Specialties ("TDS"), a subsidiary of Dentsply International, Inc., manufactures and sells post-heat treated endodontic dental files that directly compete in the marketplace with the Edge Endo EdgeFiles manufactured by Defendant.
- 24. Dentsply has suffered irreparable harm, including market price erosion and loss of market share, as well as damage to its reputation and goodwill with customers as a result of Defendant's actions.

- 25. Dentsply has suffered irreparable harm for the additional and independent reason that, in the absence of injunctive relief, US Endo is unlikely to be able to pay a damages award.
- 26. Defendant US Endo has caused and will continue to cause irreparable harm to Dentsply, its business and its reputation through their making, using, offerings for sale, sale, importation, marketing and/or distribution of products made by an infringing process, including but not limited to the EdgeFile X1, X5 and X7.
- 27. The specific instances of infringement described above are provided as examples. On information and belief, Defendant has engaged in other infringing offers for sale, uses, importations, makings, and/or sales.

COUNT I (Infringement of United States Patent No. U.S. Patent No. 8,727,773)

- 28. Dentsply realleges and incorporates herein by reference the allegations set forth in paragraphs 1-27 of this Complaint.
- 29. On information and belief US Endo has manufactured and will continue to manufacture products using a method that infringes at least claim 1 of the '773 Patent under 35 U.S.C. § 271.
- 30. On information and belief, US Endo has imported, offered to sell, sold, used, marketed and/or otherwise distributed within the United States a product which is made by a process covered by the '773 patent.
- 31. On information and belief, Defendant has infringed and continues to infringe at least one claim of the '773 Patent, pursuant to 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale, or importation of products including, but not limited to, the EdgeFile X1, X5 and X7, prior to the expiration of the '773 Patent.

- 32. On information and belief, Defendant will continue in and enlarge its infringement of the '773 patent unless and until it is preliminarily and permanently enjoined by this Court.
- 33. Dentsply has suffered irreparable harm as a result of Defendant's actions and Dentsply will continue to suffer irreparable harm unless this Court preliminarily and permanently enjoins Defendant, its agents, employees, representatives and all others acting in concert with Defendant from infringing the '773 patent.
 - 34. Dentsply has no adequate remedy at law.
- 35. This case is exceptional and Dentsply is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II (Infringement of United States Patent No. 8,562,341)

- 36. Dentsply realleges and incorporates herein by reference the allegations set forth in paragraphs 1-35 of this Complaint.
- 37. On information and belief US Endo has manufactured and will continue to manufacture products using a method that infringes at least claim 1 of the '341 Patent under 35 U.S.C. § 271.
- 38. On information and belief, US Endo has imported, offered to sell, sold, used, marketed and/or otherwise distributed within the United States a product which is made by a process covered by the '341 patent.
- 39. On information and belief, Defendant has infringed and continues to infringe at least one claim of the '341 Patent, pursuant to 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale, or importation of products including, but not limited to, the EdgeFile X1, X5 and X7, prior to the expiration of the '341 Patent.

- 40. On information and belief, Defendant will continue in and enlarge its infringement of the '341 patent unless and until it is preliminarily and permanently enjoined by this Court.
- 41. Dentsply has suffered irreparable harm as a result of Defendant's actions and Dentsply will continue to suffer irreparable harm unless this Court preliminarily and permanently enjoins Defendant, its agents, employees, representatives and all others acting in concert with Defendant from infringing the '341 patent.
 - 42. Dentsply has no adequate remedy at law.
- 43. This case is exceptional and Dentsply is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Dentsply respectfully prays that this Court:

- a. Enter a judgment that Defendant has infringed the '773 patent;
- b. Enter a judgment that Defendant has infringed the '341 patent;
- c. Grant a preliminary and permanent injunction that restrains and enjoins Defendant, its officers, directors, employees, agents, servants, parents, subsidiaries, successors, assigns, and all those in privity, concert or participation with them from directly or indirectly infringing the '773 and the '341 patents;
- d. Award Dentsply damages in an amount sufficient to compensate Dentsply for Defendant's infringement of the '773 and '341 patents, but not less than a reasonable royalty;
- e. Enter judgment that Defendant's' infringement was and is willful from the time

 Defendant became aware of the infringing nature of their products and that the Court award

treble damages for the period of such willful infringement of the '773 or '314 patent pursuant to 35 U.S.C. § 284;

- f. Award prejudgment interest to Dentsply under 35 U.S.C. § 284;
- g. Declare this case exceptional under 35 U.S.C. § 285 and award Dentsply its reasonable attorneys' fees, expenses, and costs incurred in this action; and
 - h. Grant such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Dentsply hereby demands a jury trial on all issues appropriately triable by a jury.

Dated: June 24, 2014 Respectfully submitted,

By: s/Jimmie C. Miller

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